

Application No.: 10/569,713
Filing Date: February 24, 2006

REMARKS

Applicants gratefully acknowledge the Examiner's indication that the claims are free of the prior art of record. The claims have been amended to address rejections under 35 U.S.C. § 112. A sequence listing has been prepared and is submitted herewith.

Claims 1, 4, 5, and 7 have been amended. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Specification

The typographical error noted by the Examiner on page 50, line 2 has been corrected by amendment. Withdrawal of the objection to the specification is respectfully requested.

Sequence listing

A sequence listing is submitted herewith. Page 41 of the specification has been amended to include sequence identifiers consistent with the sequence listing. This amendment directs incorporation of the sequence listing into the specification.

VERIFICATION UNDER 37 C.F.R. § 1.821 (f) & (g)

All of the sequences in the attached Sequence Listing are included in the application as filed. Pursuant to 37 C.F.R. § 1.821 (g), no new matter is being added herewith. As required under 37 C.F.R. § 1.821 (f), I hereby verify that the data on the computer readable form and the paper copies of the Sequence Listing are identical.

In view of Applicants' submission of a sequence listing, statement under 37 C.F.R. § 1.821 (f) and (g), amendment to incorporate sequence listing into the specification and amendment of the specification to show sequence identifiers, Applicants respectfully submit that the present application is in compliance with the sequence rules.

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Rejection under 35 U.S.C. § 112, first paragraph - enablement

Claims 1-7 and 28-33 are rejected under 35 U.S.C. § 112, first paragraph as containing a disclosure that is not enabling due to the absence of a recitation of wash steps.

This ground of rejection is addressed by amendment taken with the following comments.

The specification teaches at page 16, lines 17 to 21, that wash steps may be determined by the skilled artisan, and may be introduced after the incubation steps. The section also makes reference to the Examples. This section is reproduced below.

The introduction of wash steps in the method above, may be determined by the skilled artisan in accordance with commonly understood protocols in immunoassays such as ELISA and Western blots. For example, one or more wash steps may be introduced after one or more incubation step, using with a washing reagent such as a buffer. Examples of wash steps are provided in the Examples section.

According to Example 6 on page 45, washing steps can be performed after steps b), c), and d) which are incubation steps. Also, according to the Example on page 62, wash steps are performed after steps b), c), and d). Accordingly, claim 1 has been amended to include washing steps after steps b), c), and d).

In view of Applicants' amendments and comments above, withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-7 and 28-33 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states that it is unclear what relationship exists between the components and one or more probes of step (a) and the one or more tagged probes and the tag-labeled sample comprising components of step (b).

This rejection is addressed by amendment taken with the following comments. The solid support is coated either with probe or sample in step a) and thus no reaction arises in step a) between the probe and the sample since they cannot be present at the same time by virtue of the "or" wording. In order to further clarify steps a) and b) of claim 1, claim 1 has been amended to

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clarify that the incubation of step b) depends on whether a probe or a sample was applied to the solid support in step a) as follows:

- “...a) applying onto a solid support
 - i) one or more samples comprising components to be detected or
 - ii) one or more probes,
- b) incubating the solid support of step a) with:
 - i) one or more tagged probes, in the case where the solid support has one or more samples comprising components to be detected applied thereon, or
 - ii) sample comprising tag-labeled components to be detected, in the case where the solid support has one or more probes applied thereon, said incubating followed by a wash step,...”

Thus, when the solid support is coated with sample in step a), step b) specifies an incubation with one or more probes. In the alternative, when the solid support is provided with probe in step a), then step b) entails incubation with sample.

Step b) of claim 1 has been further amended to recite that the sample comprises tag-labeled components.

The Examiner also remarks that the claim should conclude with a step relating to the purpose of the method. In this regard, the Examiner’s attention is directed to the last sentence of claim 1 which recites: “...g) reading the solid support to quantitatively and/or qualitatively detect said components” as set forth in the preamble of the claim, which is believed to satisfy this requirement.

Claim 4 is rejected for the recitation of “step e1)” as lacking antecedent basis. In response, the antecedent basis for “step e1)” is found in claim 4 itself. This has been clarified by amendment of “e1” to “e-1” so that the recitation within the claim exactly matches how the method step is presented.

Claim 5 is rejected for contradiction of claim 1 in the recitation that step a) is not performed by the user. In response, claim 5 was intended to provide protection for solid supports

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preloaded with probe. Hence, step a) would certainly be performed by the method, albeit by a manufacturer and not the end user. In order to expedite prosecution, the phrase “and step a) is not performed by the user” has been deleted. It is deemed that the present recitation of “wherein the solid support is supplied with probe pre-applied” provides sufficient clarity to describe the embodiments of the invention in which the probe is preloaded.

Claim 7 has been amended to correct antecedent basis.

In view of Applicants’ amendments taken with the comments above, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants’ amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: July 29, 2008

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